SEALED

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNDER SEAL	§	
	§	**Civ. Act. No. 3-06CV1769-M**
Plaintiff	§	
	§	**PLAINTIFF'S SECOND**
	§	**AMENDED COMPLAINT**
vs.	§	**UNDER FEDERAL AND STATE**
	§	**FALSE CLAIMS ACTS**
	§	
	§	**FILED *IN CAMERA* AND UNDER**
	§	**SEAL**
UNDER SEAL	§	
	§	**JURY TRIAL DEMAND**
Defendant	§	

PLAINTIFF'S SECOND AMENDED COMPLAINT
UNDER FEDERAL AND STATE FALSE CLAIMS ACTS

FILED *IN CAMERA* AND UNDER SEAL PURSUANT
TO 31 U.S.C. § 3730(b)(2)

DO NOT ENTER IN PACER
DO NOT PLACE IN PRESS BOX

SECOND AMENDED COMPLAINT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA *ex rel.* Kevin N. Colquitt and Kevin N. Colquitt, Individually,	§	
and	§	
	§	**Civ. Act. No. 3-06CV1769-M**
STATE OF ILLINOIS *ex rel.* Kevin N. Colquitt,	§	
and	§	**PLAINTIFF'S SECOND AMENDED COMPLAINT UNDER FEDERAL AND STATE FALSE CLAIMS ACTS**
STATE OF CALIFORNIA *ex rel.* Kevin N. Colquitt,	§	
and	§	
STATE OF FLORIDA *ex rel.* Kevin N. Colquitt,	§	**JURY TRIAL DEMAND**
and	§	
STATE OF TEXAS *ex rel.* Kevin N. Colquitt,	§	**FILED *IN CAMERA* AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
and	§	
COMMONWEALTH OF MASSACHUSETTS *ex rel.* Kevin N. Colquitt,	§	**DO NOT ENTER IN PACER DO NOT PUT IN PRESS BOX**
and	§	
STATE OF TENNESSEE *ex rel.* Kevin N. Colquitt,	§	
and	§	

SECOND AMENDED COMPLAINT

STATE OF LOUISIANA *ex rel.* Kevin N. Colquitt,	§
	§
and	§
	§
COMMONWEALTH OF VIRGINIA *ex rel.* Kevin N. Colquitt,	§
	§
Plaintiffs,	§
	§
vs.	§
	§
ABBOTT LABORATORIES *f/k/a* GUIDANT CORPORATION 100 Abbott Park Road, Abbott Park, IL 60064-3500	§
	§
and	§
	§
CORDIS CORPORATION, CORDIS ENDOVASCULAR, A DIVISION OF CORDIS CORPORATION, 14201 Northwest 60th Avenue Miami Lakes, FL 33014	§
	§
and	§
	§
JOHNSON & JOHNSON 1 Johnson & Johnson Plaza New Brunswick, NJ 08933	§
	§
and	§
	§
BOSTON SCIENTIFIC CORPORATION One Boston Scientific Place Natick, MA 01760-1537	§
	§
Defendants.	§

SECOND AMENDED COMPLAINT

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Plaintiff, Kevin N. Colquitt ("Relator"), on behalf of himself, the United States of America, and the States of California, Florida, Illinois, Louisiana, Massachusetts, Tennessee, Texas, and Virginia (collectively, the "States"), brings this *qui tam* action under 31 U.S.C. §§ 3729 *et seq.* ("False Claims Act") and similar State statutes to recover damages, penalties and other remedies for violations of Medicare, Medicaid, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") and TRICARE, and alleges as follows in his Second Amended Complaint.

I. NATURE OF THE ACTION.

1. Relator's allegations are straightforward. Defendants have engaged in an off-label promotional and marketing scheme that caused and induced physicians to seek coverage and reimbursement for investigational medical devices in the form of biliary stents permanently implanted into patients for the unapproved use of treating peripheral vascular disease. The Food and Drug Administration (FDA) has not approved biliary stents for use in peripheral vasculature. Biliary stents are not vascular stents by intended use, by FDA classification, and by Medicare coverage. Indeed, the FDA concluded that biliary stents are not safe and effective for vascular use, and the Agency required Defendants to clearly and prominently warn physicians of the safety and efficacy risks to patients when marketing the stents. Defendants circumvented FDA and Medicare efforts to protect against the serious risks of permanently implanting the unapproved investigational devices in patients.

2. Defendants' fraudulent scheme to promote and market the biliary stents for unapproved vascular use targeted the FDA, healthcare providers, and Medicare. First,

Defendants filed fraudulent premarket clearance notifications with the FDA certifying that the devices were only biliary stents intended for use in the palliation of malignant strictures of the biliary tree when, in fact, Defendants intended to market the devices for use in peripheral vasculature. Second, Defendants solicited and caused physicians to prescribe the devices in an off-label manner for the treatment of peripheral vascular disease. Third, Defendants directed physicians to seek reimbursement from Medicare and Medicaid for implanting FDA premarket approved vascular stents when, in fact, biliary stents were used.

3. Medicare, its Fiscal Intermediaries and Carriers, and Medicaid have been victimized by the fraud. Medicare's Hospital Manual, Intermediary Manual, and Carriers Manual exclude coverage program-wide for devices marketed for an intended use which requires, but has not received, FDA premarket approval. Under FDA and Medicare rules, Defendants' biliary stents are investigational devices that are not medically reasonable and necessary. Coverage was excluded program-wide for "medical procedures or services performed using devices which have ***not been approved for marketing by the FDA***." Fiscal Intermediaries and Carriers incorporated this coverage exclusion in local coverage determinations applicable in every State. Fiscal Intermediaries and Carriers also made clear that coverage was restricted to FDA premarket approved vascular stents, not investigational biliary stents marketed off-label for an unapproved intended use.

4. Several thousand patients are diagnosed annually with terminal biliary cancer resulting in poor flow of the bile duct. Life expectancy is limited. Patients experience drainage issues in the bile duct resulting in painful, ancillary medical symptoms. A biliary

stent is a temporary, palliative medical device implanted in the bile duct to keep it open. 21 C.F.R. § 876.5010(a). It is a Class II device requiring premarket clearance following notice to FDA in the form of a section 510(k) premarket notification certifying to the substantial equivalence to intended use of a predicate device. 21 C.F.R. § 876.5010(b). Defendants filed with FDA approximately eighty section 510(k) premarket notifications for biliary stents. Premarket clearance "does not in any way denote official approval of the device[s]." 21 C.F.R. § 807.97. By regulation, a representation creating an impression of official FDA approval of a device with only a premarket clearance is misleading and is considered misbranding. 21 C.F.R. § 807.97.

5. Vascular stents are functionally and compositionally different than biliary stents. Vascular stents (also known as intravascular or endovascular stents) are classified by the FDA as Class III medical devices that pose significant risks to patients. They are implanted permanently into patients' vascular systems to treat peripheral vascular disease by enhancing vessel patency and reducing early restenosis over the life of the device. In contrast to the few thousand patients annually with cancer in the biliary tree, hundreds of thousands of patients are diagnosed annually with vascular disease. Most live decades.

6. Unlike biliary stents, vascular stents require premarket approval (PMA) from the FDA before marketing the devices. Premarket approval is the most stringent regulatory review reserved for high-risk devices. It requires device manufacturers to clinically establish the safety and efficacy of the devices in patients. It is a lengthy, costly process which Defendants conspired to avoid. FDA has approved seven premarket approval applications authorizing the

marketing of vascular stents for use in the vascular system to treat peripheral vascular disease. Several of these FDA approved vascular stents have been commercially available throughout the period covered by this Second Amended Complaint.

7. Recognizing an opportunity, Defendants developed stents with the intent to promote and market the devices for the treatment of vascular disease. They filed for patent protection with the United States Patent and Trademark Office certifying to claims that the devices were intended for vascular disease and use in the human vascular system. No claims were made for palliation of malignant strictures of the biliary tree. Then they knowingly filed fraudulent section 510(k) premarket clearance notifications with the FDA falsely certifying that the devices were only biliary stents for use in the palliation of malignant biliary strictures. In doing so, Defendants entirely circumvented the required premarket approval process for Class III vascular stents.

8. The FDA granted premarket clearance for the biliary stents under section 510(k) limited to palliation of malignant strictures of the biliary tree. None of the devices was premarket approved by the FDA as a Class III vascular stent intended for use in the peripheral vascular system. Instead, the FDA required Defendants to prominently disclose in labeling, marketing and promotional materials that "[t]he safety and effectiveness of this device for use in the vascular system have not been established." The premarket clearance letters from the FDA plainly warned Defendants of the regulation prohibition that the biliary stents are misbranded if represented in any capacity to be a device approved by the FDA. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 807.97.

9. Enabled with section 510(k) premarket clearances for the biliary stents, Defendants promoted and marketed the devices off-label as vascular stents intended to treat peripheral vascular disease. Relator's evidence as a territory sales manager is incontrovertible, for example:

A. Defendants instructed sales representatives to target physicians specializing in peripheral vascular disease to induce the use of the Class II biliary stents as unapproved Class III vascular stent intended for vascular disease.

B. Defendants directly or indirectly sponsored or funded studies of the off-label use of the biliary stents to treat peripheral vascular disease and provided the study information to sales representatives for use in marketing and promoting the devices to vascular physicians.

C. Defendants extensively marketed and promoted the devices in print and electronic advertisements targeting physicians with vascular specialization. The objective intent of the marketing was to solicit the use of the devices as intended for the vascular system. Essentially no print and electronic marketing of the biliary stents targeted gastroenterologists and hepatologists (physicians specializing in biliary tree disorders).

D. Defendants provided unsolicited marketing and promotional literature to physicians concerning the off-label use of the unapproved biliary stents to treat vascular disease. Among the unsolicited literature was information

advising physicians how to develop and expand a peripheral vascular practice, thereby encouraging the unapproved use of the biliary stents.

E. Defendants prepared patient "advisory" letters and similar documents concerning the health risks of undiagnosed and untreated peripheral vascular disease. The documents were distributed to vascular specialists, without solicitation, to send to patients to generate patient interest in peripheral vascular disease and to induce the unapproved use of the biliary stents. The unsolicited documents warned patients of severe, life-threatening medical consequences associated with undiagnosed and untreated peripheral vascular disease such as "kidney damage or failure, tissue damage and, in extreme cases, amputation of affected extremities."

F. Sales representatives were given mandatory quotas requiring them to sell the biliary stents off-label simply to satisfy the quota. Sales representatives were compensated with bonuses for off-label sales.

G. Biliary stents were consigned to healthcare providers to promote usage. Stent inventory was allocated to hospital departments that do not perform biliary procedures, but do perform vascular stenting. Utilization rates were closely monitored by sales representatives. The information was reported regularly to management for use in developing business plans and utilization rate projections based on the off-label use of the biliary stents.

H. Defendants provided reimbursement guidelines and manuals to physicians that instructed physicians to falsely code reimbursement claims using procedural codes for approved vascular stents, even though an unapproved biliary stent was utilized.

10. Defendants' marketing and promotion of the unapproved biliary stents as Class III vascular stents intended for use in the vascular system without premarket approval of the FDA renders the biliary stents adulterated medical devices under 21 U.S.C. § 351(f) and non-covered by Medicare and Medicaid.

11. The acts and practices described herein violate 18 U.S.C. § 1001 which provides, in relevant part, criminal sanctions for any person who knowingly and willfully falsifies or conceals a material fact; makes materially false statements; or makes a false document containing a materially false statement in any matter within the jurisdiction of the executive, legislative, or judicial branch. The acts and practices also violate 18 U.S.C. §§ 1035, 1343, and 1347 based on Defendants false statements and representations in connection with the delivery of, or payment for, health care benefits, items, or services. Defendants' violations of these Federal statutes include, for example, (a) filing section 510(k) premarket clearance notifications with the FDA that knowingly and willfully falsely certify and conceal the intended use of the devices as demonstrated by Defendants' conduct, acts, and statements before and after filing with the FDA, and (b) making false statements and representations that caused healthcare providers to submit false claims for coverage and reimbursement.

12. Defendants' scheme also violated statutory requirements to conduct post-market surveillance of medical devices that are marketed and promoted for a Class III indication requiring premarket approval. Pursuant to the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997, Defendants avoidance of statutorily required post-market surveillance further concealed Defendants' fraudulent scheme and the true extent of the safety and efficacy issues raised for beneficiaries by marketing the unapproved biliary stents as intended for use in the vascular system.

13. Defendants succeeded in the off-label scheme. In excess of 700 biliary stents product codes made by Defendants have been promoted and marketed off-label for treating peripheral vascular disease, even though more than 500 of these biliary stent product codes cannot be used in the biliary tree due to the length and diameter of the device. Indeed, virtually all of the approximate 150,000 stents implanted in patients each year to treat vascular disease are adulterated and misbranded biliary stents whose investigational use is not authorized by Federal standards based on Defendants' failure to establish that the devices are safe and effective under Federal law. Under well-established legal principles, Relator seeks to recover on behalf of the United States and the States for the false claims for coverage and reimbursement of the biliary stents and associated noncovered services which were induced by the illegal, off-label promotion and marketing. Applicable statutory law and Medicare coverage and reimbursement policies clearly preclude coverage for non-FDA approved investigational devices.

14. Defendants' scheme has injured program beneficiaries who have received implants of the unapproved, investigational stents in their peripheral vasculature without the statutory-mandated safety net of clinically established safety and efficacy. The impact on beneficiaries' health and safety cannot be overstated as reflected in adverse events reported by healthcare providers. As a direct consequence of Defendants' scheme, thousands of severe adverse events have been reported for patients who had unapproved biliary stents permanently implanted in their vascular systems. Many thousands more have not been reported.

15. The adverse events reported include death, fractures of the devices after implantation, migration and dislodgement of the devices after implantation, arterial dissection and occlusion, arterial and stent embolizations, aneurysms, acute renal insufficiency, amputations, air embolisms, fistulization, strokes, late restenosis, allergic reactions, infections, clots, internal bleeding, and persistent vessel spasms, among other serious medical conditions.

16. In addition, entire product lines of the biliary stents have been recalled by the FDA and manufacturers because the investigational devices have not been demonstrated to be safe and effective for use in the vascular system – a belated outcome of grave significance for beneficiaries already implanted with the defective devices. The adverse events and product recalls of the devices demonstrate that the safety and efficacy of biliary stents have not been demonstrated to Federal standards, thereby resulting in increased mortality and morbidity due to the investigational usage in patients with peripheral vascular disease due to Defendants' illegal off-label marketing and promoting of the devices.

II. PARTIES.

17. Relator, Kevin N. Colquitt, is an individual citizen of the United States and a current resident of the State of Maryland. By virtue of his previous marketing positions with Defendant Guidant Corporation d/b/a Abbott Laboratories he became aware of the pervasive off-label marketing and promotion set forth herein. Relator has direct and independent knowledge of the information on which the allegations in this Complaint are based. He is an original source of information given to the United States regarding Defendants knowing pursuit of illegal conduct in violation of Federal and State laws and regulations that resulted in the payment of false or fraudulent claims. Relator has provided the Attorney General of the United States and the United States Attorney for the Northern District of Texas a statement of material evidence and documentary evidence supporting the claims of wrongdoing.

18. Defendant Abbott Laboratories f/k/a/ Guidant Corporation ("Defendant Guidant"), is an Illinois corporation which has its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. Directly and through its division, Abbott Vascular Defendant Abbott has conducted the off-label, unlawful marketing and promotion of biliary stents for use in the vascular system set forth herein. References to Defendant Abbott Vascular in this Second Amended Complaint include Abbott Laboratories and its Abbott Vascular division. References to Defendant Guidant Corporation in this Second Amended Complaint include its Endovascular Solutions division, which was acquired by Defendant Abbott Vascular, as well as Defendant Abbott Vascular. Defendant Abbott Vascular may be

served by serving its agent for service of process, CT Corporation System at 350 North St. Paul, #2900, Dallas, Texas 75201.

19. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation which has its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, NJ 08933. Defendant J&J is the parent company and holding company for its alter ego Defendant Cordis Corporation and Cordis Endovascular (collectively "Defendant Cordis Endovascular"). Defendant J&J dominates and controls the policies of Defendant Cordis Endovascular, and it is legally responsible for the actions of its alter ego. Directly and through the actions of Defendant Cordis Endovascular, Defendant J&J has conducted the off-label, unlawful marketing and promotion of biliary stents for use in the vascular system set forth herein. Defendant J&J may be served by serving its agent for service of process, CT Corporation System at 350 North St. Paul, #2900, Dallas, Texas 75201.

20. Defendant Cordis Corporation ("Cordis") is a Florida corporation which has its principal place of business at 14201 Northwest 60th Avenue, Miami Lakes, Florida 33014. Directly or through its division Cordis Endovascular, Defendant Cordis has conducted the off-label, unlawful marketing and promotion of biliary stents for use in the vascular system with the knowledge and approval of Defendant J&J. Defendant Cordis Endovascular is the alter ego of Defendant J&J, which manages and dominates the policies of Defendant Cordis Endovascular. Defendant Cordis Endovascular may be served by serving its agent for service of process, CT Corporation System, 1200 South Pine Island Road, Plantation, Florida 33324.

21. Defendant Boston Scientific Corporation ("Boston Scientific") is a Delaware corporation which has its principal place of business at One Boston Scientific Place, Natick, Massachusetts 01760-1537. Defendant BSC has conducted the off-label, unlawful marketing and promotion of biliary stents for use in the vascular system set forth herein. Defendant BSC may be served by serving its agent for service of process, Corporation Service Corporation at 701 Brazos Street, Suite 1050, Austin, Texas 78701.

III. JURISDICTION AND VENUE.

22. This Court possesses subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732, because Relator seek remedies on behalf of the United States and the States for Defendants' violations of 31 U.S.C. § 3729 some of which occurred in the Northern District of Texas, and because the Defendants transact substantial business within the Northern District of Texas.

23. This Court has pendant jurisdiction over the State FCA claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367.

24. The Complaint has been filed timely within the period prescribed by 31 U.S.C. § 3731(b).

25. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c) because at least one of the Defendants resides, transacts business, or is qualified to do business in this District. In addition, the acts proscribed by the False Claims Act were committed by Defendants in this judicial district.

IV. FEDERAL REGULATION OF MEDICAL DEVICES.

26. The Center for Devices and Radiological Health (CDRH) is the FDA office with responsibility over protecting the health and safety of American consumers by ensuring that medical devices designed for use in the human body are safe and effective for the intended use and accurately labeled under Federal requirements.

27. A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. . . ." 21 U.S.C. § 321(h).

28. Following the passage of the Medical Device Amendments of 1976, the FDA established three risk-based classifications for medical devices. Classes I, II, and III represent low, moderate, and high-risk categories based on the intended use of the device.

29. Class I devices are those for which "aherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness," such as tongue depressors and elastic bandages. 42 C.F.R. § 405.201(b).

30. Class II devices are those for which general controls are insufficient to provide reasonable assurance of safety and effectiveness. They pose a moderate risk to patients, such as electronic thermometers, powered wheelchairs, and blood pressure cuffs, thereby necessitating special controls. 42 C.F.R. § 405.201(b).

31. A Class II device must obtain premarket clearance from the FDA before it can be promoted and marketed. This requires the device manufacturer to file a section 510(k) premarket clearance notification with FDA at least ninety (90) days before introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use. 21 U.S.C. § 360(k); 21 C.F.R. § 807.81. The FDA must then issue a premarket clearance letter permitting the device manufacturer to market the device for indicated uses and subject to limiting conditions imposed by the FDA.

32. In the section 510(k) premarket clearance notification, the device manufacturer is required to certify to the intended use of the device, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. 21 C.F.R. § 807.92(a)(5).

33. The "intended use" of a device is defined in 21 C.F.R. § 801.4 as:

> the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. . . . But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

34. The FDA accepts the manufacturer's certified statement of intended use for purposes of classifying the device, reflecting the general right of the manufacturer to market the device provided it is substantially equivalent to a predicate device and is marketed based on the same intended use. 21 U.S.C. § 360c(i)(1)(A). If the FDA believes that there is a reasonable likelihood that the device will be used in a manner not included in the manufacturer's labeling, and that such use could cause harm to the patient, the FDA may require the manufacturer to place a warning in the labeling against such off-label use. 21 U.S.C. § 360c(i)(1)(A)(E).

35. The section 510(k) premarket clearance notification must include data demonstrating that the device is substantially equivalent to a predicate device promoted and marketed in interstate commence prior to the Medical Device Amendments of 1976. A medical device is substantially equivalent to a predicate device only if the intended use is the same as that of the predicate device. If the intended use is different, the device is not substantially equivalent. The device manufacturer is prohibited by law from promoting and marketing the device in interstate commerce for an intended use not cleared in the premarket clearance notification. Marketing the device for a different intended use makes the device misbranded and adulterated.

36. Consistent with the Safe Medical Devices Act of 1990, the FDA requires applicants filing a section 510(k) premarket clearance notification to summarize the safety and effectiveness information in the notification, or certify in writing as to the availability of that data. Device manufacturers also are required to certify to the truthfulness and accuracy of the

section 510(k) premarket clearance notification by stating "I certify in my capacity as (title) for (manufacturer's name), I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted." 21 C.F.R. § 807.87(k).

37. Class III devices are those which general or specific controls do not assure safe and effective use. They generally include life-supporting and life-sustaining devices which present a high or unreasonable risk of injury or illness to the patient, such as pacemakers, heart valves, and silicone gel-filled breast implants. Devices first introduced after May 1976 were presumed to be Class III devices by operation of law. 21 U.S.C. § 360c(f)(1).

38. A Class III device requires premarket approval of the intended use of the device by the FDA prior to promoting and marketing the device. Premarket approval is the most stringent level of device regulation required by the FDA. It requires the device manufacturer to provide sufficient scientific evidence to establish the safety and efficacy of the medical device for its intended uses demonstrated by clinically significant results. 21 C.F.R. §§ 814 & 860.7 *et seq.* In addition to limiting approval to devices demonstrated to be safe and effective, the stated purpose of premarket approval is "[t]o ensure the disapproval of PMA's for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval." 21 C.F.R. § 814.2.

39. Safety and effectiveness is a substantially higher standard than substantial equivalence in a section 510(k) premarket notification. As part of the premarket approval process, a manufacturer must furnish detailed information about the device's testing, design,

components, performance standards, manufacturing, packaging, and labeling sufficient to reasonably assure the FDA that the device is safe and effective. Premarket approval routinely requires the manufacturer to conduct a well controlled clinical trial of the device in order to demonstrate safety and effectiveness. In order to conduct such a clinical trial, the manufacturer must apply for an investigational device exemption ("IDE"), which allows the manufacturer to legally ship the device for the purposes of conducting the trial. 21 U.S.C. 360j(g); 42 C.F.R. § 405.201(b).

40. FDA further categorizes Class III devices as either Category A or Category B. Category A devices are innovative technologies "for which 'absolute risk' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective)." 42 C.F.R. § 405.201(b). Category A devices are considered to be experimental and investigational. Category B devices are devices "for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type." *Id.* Category B devices are considered to be non-experimental, but still investigational.

41. Based on well-established procedures for reviewing a premarket approval application, the FDA issues to the applicant an "approvable letter" or "not approvable letter" for the medical device. 21 C.F.R. § 814.44(e) & (f). Upon receiving an approvable letter from

the FDA, the device manufacturer's marketing is limited to the labeling claims and intended use specified in the approvable letter.

42. Upon receiving section 510(k) premarket clearance, the device manufacturer's promotion and marketing for the device is limited to the labeling claims and the intended use cleared by the FDA.

43. Device manufacturers are not permitted to promote and market a device off-label, meaning for indications not specifically cleared (510k notification) or approved (PMA) by the FDA. 21 U.S.C. §§ 312.7 & 331(a), (d).

44. A biliary stent that has been cleared for marketing by the FDA for a biliary indication "does not in any way denote official approval of the device" by the FDA. 21 C.F.R. § 807.97. Representations that create the impression of official approval of a device because of complying with the premarket notification regulations are misleading and constitute misbranding. 21 C.F.R. § 807.97.

V. FEDERAL REGULATION OF BILIARY AND VASCULAR STENTS.

45. A stent is a tubular metal scaffolding placed under x-ray guidance inside tubular structures (e.g., blood vessels, bile ducts, etc.) of the body.

46. The FDA has premarket approved or premarket cleared various stents for use in the human body such as coronary stents, biliary stents, vaginal stents, ureteral stents, and vascular stents. Each stent type is functionally and compositionally different based on the intended use in the body, design specifications (e.g., length and diameter), composite material (e.g., bare metal, silicone, plastic, drug eluding), method of placement, and performance characteristics

(e.g., balloon expanding or self-expanding). Because of these differences, stents types are not interchangeable, that is, an ureteral stent cannot be placed in a coronary artery in lieu of an FDA premarket approved coronary stent. Different safety and efficacy risks are presented by each stent, and the FDA classifies stents accordingly.

47. A biliary stent is a Class II medical device. 21 C.F.R. § 876.5010. Federal regulations define a biliary stent as "a tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, or for preventing stricture of the bile duct. This generic type of device may include a bile collecting bag that is attached to the biliary catheter by a connector and fastened to the patient by a strap." 21 C.F.R. § 876.5010(a). *See* Food and Drug Administration Center for Devices and Radiological Health, *Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents*, at 2 (Feb. 5, 1998).

48. Biliary stents generally are implanted in patients by gastroenterologists and interventional radiologists as palliative measures for patients with malignant biliary strictures in the pancreas, stomach, or liver. Several thousand patients each year are diagnosed with this type of terminal cancer including cholangiocarcinoma, pancreatic carcinoma, ampullary carcinoma, metastases, and gall bladder carcinoma. Obstructions prevent normal drainage of bile into the digestive tract, leading to pain and discomfort. Life expectancy is measured in months. Biliary stents relieve a symptom of cancer resulting from the obstructions, but do not cure the disease. Because biliary stents are implanted in patients with short life expectancy, no long term clinical studies are required to establish the safety and effectiveness of the devices.

FDA thus categorizes biliary stents as Class II devices reflecting the moderate risk associated with the short-term use of the devices.

49. A peripheral vascular stent is a Class III medical device. FDA defines these devices as "a synthetic tubular structure intended for permanent implant in native or graft vasculature. The stent is designed to provide mechanical radial support after deployment; this support is meant to enhance vessel patency over the life of the device." *See* Food and Drug Administration Center for Devices and Radiological Health, *Guidance for Industry and Staff: Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems*, at 2 (Jan. 13, 2005). FDA classifies peripheral vascular stents based on their intended use anatomically in the human body, for example, placement in the iliac artery, renal artery, or superficial femoral artery.

50. Peripheral vascular stents are not palliative. They are intended to mitigate, treat, cure, or prevent peripheral vascular disease (PVD) by increasing vessel patency. It is estimated that 20 and 30 million Americans have PVD caused by obstructions of peripheral arteries resulting from atherosclerosis, inflammatory processes leading to stenosis, embolisms, or thrombus formation. Patients are not terminal. Most patients have a long life-expectancy with medication and life style changes.

51. Vascular stents are permanent implants. Because PVD patients have a long life expectancy, and because vascular stents generally cannot be explanted, the safety and efficacy of vascular stents must be clinically established by the device manufacturer. The FDA, therefore, classifies vascular stents intended for use in the vascular system as Class III medical

devices requiring premarket approval. A stent marketed as intended for use in the vascular system cannot be cleared for marketing through a section 510(k) premarket clearance.

52. Seven peripheral vascular stents have been approved by the FDA for specific conditions of use in the vascular system including renal arteries, iliac arteries, and the superficial femoral artery. Table 1 lists each vascular stent, the manufacturer, and the approved indications for use, and the premarket approval date.

TABLE 1
FDA APPROVED CLASS III PERIPHERAL VASCULAR STENTS

Name	Manufacturer	Approved Indications	Date	PMA
Palmaz Balloon Expandable Stent	Defendant Cordis Endovascular	Renal artery and illiac artery	09/27/1991	P890017
Wallstent Illiac Endoprosthesis	Defendant Boston Scientific	Illiac artery	05/28/1996	P940019
Intracoil	EV3	Superficial femoral artery	04/03/2002	P000033
Medtronic AVE Bridge	Medtronic	Renal artery	12/18/2002	P020007
SMART and SMART Control Nitinol Stent System	Defendant Cordis Endovascular	Illiac artery	08/12/2003	P020036
Viabahn Endoprosthesis	W.L. Gore	Superficial femoral artery	06/14/2005	P040037
Zilver	Cook Medical	Illiac artery	06/26/2006	P050017

53. In contrast, Defendants filed with FDA approximately eighty section 510(k) premarket clearance notifications for biliary stents resulting in approximately 35 different biliary stent product lines. From this, more than 700 Class II biliary stent product codes have been manufactured, marketed, and promoted by Defendants off-label as Class III vascular stents intended for the treatment of vascular disease. More than 500 models of these are of a

size (length and diameter) that cannot be used in the biliary system, but can be used in the vascular system only. None of these medical devices has received FDA approval as Class III vascular stents based on demonstrated safety and efficacy. Exhibit 1 is a table listing each biliary stent manufactured by Defendants which, based on reported design specifications, generally cannot be used in the biliary tree but could be used in the vascular system.

VI. DEFENDANTS' FALSE CERTIFICATIONS TO FDA.

54. Defendants' scheme involved the false certification to the FDA as to (a) the type of device for which they sought section 510(k) premarket clearance, and (b) the intended use of the device.

55. Defendants developed hundreds of stents during and after the 1990s following the FDA's premarket approval of the Palmaz vascular stent in 1991. The stents were developed with the intention of marketing and promoting them as Class III devices for the treatment of vascular disease. This intention is reflected in promotional documents and patent applications filed with the United States Patent and Trademark Office. Defendants obtained patent protection for the stents based on claims that the devices are intended for the treatment of vascular disease and/or use in the human vascular system. No claims were made for use as a palliative measure for malignant biliary cancer.

56. Defendants then filed section 510(k) premarket clearance notifications with the FDA asserting that the intended uses were only palliative for the biliary tree. The section 510(k) premarket notifications falsely identified the devices as Class II biliary stents intended for the palliation of malignant cancer in the biliary tree. Defendants falsely certified as to the

type of device and intended use in order to induce FDA clearance. The false certifications were made to deliberately avoid undergoing premarket approval and conducting expensive and time consuming clinical trials requiring Defendants to demonstrate that the devices are safe and effective based on valid scientific evidence. Several examples illustrate the scheme.

A. Examples of Defendant Cordis Endovascular's False FDA Filings.

57. On June 19, 2000, Defendant Cordis Endovascular filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Cordis S.M.A.R.T. Nitinol Stent Transhepatic Biliary System (No. K001843) as a Class II biliary stent. Defendant Cordis Endovascular falsely certified to FDA that "[t]he Cordis S.M.A.R.T. Nitinol Stent Transhepatic Biliary System is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose that the Cordis S.M.A.R.T Nitinol Stent Transhepatic Biliary System was intended to be used as a vascular stent in the vascular system. Based on Defendant Cordis Endovascular's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Cordis Endovascular prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

58. As demonstrated by the design of the Cordis S.M.A.R.T. Nitinol Stent Transhepatic Biliary System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Cordis Endovascular falsely certified the type of device, intentionally misstated the intended use, and intentionally

omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

59. On February 9, 2001, Defendant Cordis Endovascular filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Palmaz Genesis Transhepatic Stent and Delivery System (No. K010411) as a Class II biliary stent. Defendant Cordis Endovascular falsely certified to FDA that "the Palmaz Genesis Transhepatic Stent and Delivery System is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose that the Cordis Palmaz Genesis Transhepatic Stent and Delivery System was intended to be used as a vascular stent in the vascular system. Based on Defendant Cordis Endovascular's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Cordis Endovascular's prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

60. As demonstrated by both the design of the Palmaz Genesis Transhepatic Stent and Delivery System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Cordis Endovascular falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended to be used as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

61. On February 12, 2001, Defendant Cordis Endovascular filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Precise

RX Nitinol Stent Transhepatic Biliary System (No. K010445) as a Class II biliary stent. Defendant Cordis Endovascular falsely certified to FDA that Precise RX Nitinol Stent Transhepatic Biliary System "is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose that the Precise RX Nitinol Stent Transhepatic Biliary System was intended to be used as a vascular stent in the vascular system. Based on Defendant Cordis Endovascular's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Cordis Endovascular prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

62. As demonstrated by the design of the Precise RX Nitinol Stent Transhepatic Biliary System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Cordis Endovascular falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended to be used as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

63. On June 29, 2001, Defendant Cordis Endovascular filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Palmaz Genesis Transhepatic Biliary Stent on Slalom .018 Delivery System (No. K012056) as a Class II biliary stent. Defendant Cordis Endovascular falsely certified to FDA that Palmaz Genesis Transhepatic Biliary Stent on Slalom .018 Delivery System "is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance

notification concealed and failed to disclose that the Palmaz Genesis Transhepatic Biliary Stent on Slalom .018 Delivery System was intended to be used as a vascular stent in the vascular system. Based on Defendant Cordis Endovascular's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Cordis Endovascular prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

64. As demonstrated by the design of the Palmaz Genesis Transhepatic Biliary Stent on Slalom .018 Delivery System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Cordis Endovascular falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

65. On August 9, 2001, Defendant Cordis Endovascular filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Palmaz Genesis Transhepatic Biliary Stent on Opta Pro .035 Delivery System (No. K012590) as a Class II biliary stent. Defendant Cordis Endovascular falsely certified to FDA that Palmaz Genesis Transhepatic Biliary Stent on Opta Pro .035 Delivery System "is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose that the Palmaz Genesis Transhepatic Biliary Stent on Opta Pro .035 Delivery System was intended to be used as a vascular stent in the vascular system. Based on Defendant Cordis Endovascular's false certifications and

statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Cordis Endovascular prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

66. As demonstrated by the design of the Palmaz Genesis Transhepatic Biliary Stent on Opta Pro .035 Delivery System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Cordis Endovascular falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

67. On June 11, 2004, Defendant Cordis Endovascular filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Cordis Palmaz Blue .018 Transhepatic Biliary Stent System (No. K040413) as a Class II biliary stent. Defendant Cordis Endovascular falsely certified to FDA that Cordis Palmaz Blue .018 Transhepatic Biliary Stent System "is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose that the Cordis Palmaz Blue .018 Transhepatic Biliary Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Cordis Endovascular's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Cordis Endovascular prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

68. As demonstrated by the design of the Cordis Palmaz Blue .018 Transhepatic Biliary Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Cordis Endovascular falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

69. On March 30, 2006, Defendant Cordis Endovascular filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Cordis Palmaz Blue .014 Transhepatic Biliary Stent System (No. K060877) as a Class II biliary stent. Defendant Cordis Endovascular falsely certified to FDA that Cordis Palmaz Blue .014 Transhepatic Biliary Stent System "is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose that the Cordis Palmaz Blue .014 Transhepatic Biliary Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Cordis Endovascular's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Cordis Endovascular prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

70. As demonstrated by the design of the Cordis Palmaz Blue .014 Transhepatic Biliary Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Cordis Endovascular falsely certified the type of device, intentionally misstated the intended use, and intentionally

omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

71. In each section 510(k) premarket clearance notification submitted to the FDA, Defendant Cordis Endovascular certified that "all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." 21 C.F.R. § 807.87(k).

72. Following Defendant Cordis Endovascular's false certifications in the section 510(k) premarket clearance notifications, the FDA issued clearance letters notifying Defendant Cordis Endovascular in writing of a "reasonable likelihood that this device will be use for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 512(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling: The safety and effectiveness of this device for use in the vascular system has not been established. Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print." None of the devices was approved by the FDA for promotion or marketing as an FDA approved vascular stent intended to be used in the vascular system and established to be safe and effective to treat peripheral vascular disease.

B. Examples of Defendant Boston Scientific's False FDA Filings.

73. On August 19, 2002, Defendant Boston Scientific filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Express Biliary

LD Stent (No. K021630) as a Class II biliary stent. Defendant Boston Scientific falsely certified to FDA that Express Biliary LD Stent "is indicated for treatment of biliary strictures produced by malignant neoplasms." The section 510(k) premarket clearance notification concealed and failed to disclose that the Express Biliary LD Stent was intended to be used as a vascular stent in the vascular system. Based on Defendant Boston Scientific's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Boston Scientific prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

74. As demonstrated by the design of the Express Biliary LD Stent and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Boston Scientific falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

75. On June 27, 2003, Defendant Boston Scientific filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Sentinol Nitinol Biliary Stent System (No. K032025) as a Class II biliary stent. Defendant Boston Scientific falsely certified to FDA that Sentinol Nitinol Biliary Stent System "is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose the Sentinol Nitinol Biliary Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Boston

Scientific's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Boston Scientific prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

76. As demonstrated by the design of the Sentinol Nitinol Biliary Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Boston Scientific falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

77. In each section 510(k) notification filed with the FDA, Defendant Boston Scientific certified that "all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." 21 C.F.R. § 807.87(k).

78. Following Defendant Boston Scientific's false certifications in section 510(k) premarket clearance notification, the FDA issued clearance letters notifying Defendant Boston Scientific in writing of a "reasonable likelihood that this device will be use for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 512(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling: The safety and effectiveness of this device for use in the vascular system has not been established. Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar

point size, and in bold print." None of the devices was approved by the FDA for promotion or marketing as an FDA approved vascular stent intended to be used in the vascular system and established to be safe and effective to treat peripheral vascular disease.

C. Examples of Defendant Guidant's False FDA Filings.

79. On March 14, 2000, Defendant Guidant filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Dynalink Biliary Self-Expanding Stent System (No. K002143) as a Class II biliary stent. Defendant Guidant falsely certified to FDA that Dynalink Biliary Self-Expanding Stent System "is intended for palliation of malignant strictures in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose the Dynalink Biliary Self-Expanding Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Guidant's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Guidant prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

80. As demonstrated by the design of the Dynalink Biliary Self-Expanding Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Guidant falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

81. On March 7, 2001, Defendant Guidant filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the RX Herculink Plus Biliary Stent System (No. K010684) as a Class II biliary stent. Defendant Guidant falsely certified to FDA that RX Herculink Plus Biliary Stent System "is intended for palliation of malignant strictures in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose the RX Herculink Plus Biliary Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Guidant's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Guidant prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

82. As demonstrated by the design of the RX Herculink Plus Biliary Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Guidant falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

83. On April 4, 2001, Defendant Guidant filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Omnilink .018 Biliary Stent System (No. K011039) as a Class II biliary stent. Defendant Guidant falsely certified to FDA that Omnilink .018 Biliary Stent System "is intended for palliation of malignant strictures in the biliary tree." The section 510(k) premarket clearance notification concealed and failed

to disclose the Omnilink .018 Biliary Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Guidant's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Guidant prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

84. As demonstrated by the design of the Omnilink .018 Biliary Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Guidant falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

85. On May 15, 2001, Defendant Guidant filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Omnilink .035 Biliary Stent System (No. K011506) as a Class II biliary stent. Defendant Guidant falsely certified to FDA that Omnilink .035 Biliary Stent System "is intended for palliation of malignant strictures in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose the Omnilink .035 Biliary Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Guidant's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Guidant prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

86. As demonstrated by the design of the Omnilink .035 Biliary Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Guidant falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact that the device was intended for use as an unapproved vascular stent in the vascular system, thereby rendering the device adulterated and misbranded.

87. On October 22, 2003, Defendant Guidant filed with the FDA a section 510(k) premarket clearance notification of intent to promote and market the Absolute .035 Biliary Self-Expanding Stent System (No. K033393) as a Class II biliary stent. Defendant Guidant falsely certified to FDA that Absolute .035 Biliary Self-Expanding Stent System "is intended for palliation of malignant strictures in the biliary tree." The section 510(k) premarket clearance notification concealed and failed to disclose that the Absolute .035 Biliary Self-Expanding Stent System was intended to be used as a vascular stent in the vascular system. Based on Defendant Guidant's false certifications and statements, the FDA issued a premarket clearance letter limited to the intended use and imposing restrictions on Defendant Guidant prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

88. As demonstrated by the design of the Absolute .035 Biliary Self-Expanding Stent System and the subsequent promotion and marketing of the device, the device was objectively intended to be used as a Class III vascular stent. Defendant Guidant falsely certified the type of device, intentionally misstated the intended use, and intentionally omitted the material fact